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09/857,233

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Jamey D. Marth

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05/30/2006

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EXAMINER

SAUNDERS, DAVID A

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,233

Applicant(s)

MARTH ET AL.

Examiner

David A. Saunders, PhD

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26,35-37 and 52-69 is/are pending in the application.
- 4a) Of the above claim(s) 59-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,35-37,52-58 and 68-696 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/01/01 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/21/06 has been entered.

Claims 26, 35-37 and 52-69 are pending. Claims 26, 35-37, 52-58 and 68-69 are under examination. Since no linking claim is allowable, Claims 59-67 are withdrawn; these claims pertain to non-elected Groups XVI-XVIII.

The 112, first para. scope of enablement rejection of record is withdrawn, since applicant has taught the diagnosis of a deficiency in immune cell function using a reagent that detects a normal amount of an oligosaccharide determinant on normal cells and that detects a decreased amount of the oligosaccharide determinant on diseased cells (e.g. spec pg 28, lines 16-18; pg 30, lines 3-8 and 28-29). Conversely, applicant has taught the diagnosis of a deficiency in immune cell function using a reagent that detects an absent/decreased amount of an oligosaccharide determinant on normal cells and that detects an increased amount of the oligosaccharide determinant on diseased cells (e.g. spec pg 30, lines 20-24).

New grounds of objection/rejection are stated infra.

The drawings are objected to because in Figure 17, what is presented on the left side is designated as "Diagnostic Reagent 1" and this corresponds to the what the claims recite as a "second type of diagnostic reagent". Conversely, what is presented on the right side is

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designated as “Diagnostic Reagent 2” and this corresponds to the what the claims recite as a “first type of diagnostic reagent”. Reciting “Reagent 1” as corresponding to the “second type” and reciting “Reagent 2” as corresponding to the “first type” obfuscates the nature of the invention. Thus applicant is required to change the designations of the Reagents shown in Fig. 17

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The disclosure is objected to because of the following informalities: The brief description of Fig. 17 at pg 11, lines 5-15 and the discussion thereof at pg 16, lines 5-27 must be modified to reflect the changes required supra for Fig. 17.

Appropriate correction is required.

Claim 58 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 58 “the reduced amount of core 2 type O-glycan” and “the immune cell” lack antecedent basis.

Claims 26, 35-37, 52-58 and 68-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Ellis et al (Immunity, 9, 881, 1998).

The reference is cited under 102(a), since it has authors who are not inventors. The exact date of publication in December 1998 cannot be determined; however it is assumed to predate the 12/21 and 12/30 filing dates of applicant’s ‘680 and ‘174 provisional applications. It is noted that the earlier filed ‘671 provisional application cannot support instant claim 26.

Ellis et al show all aspects of the instant invention wherein the mammal is a mouse, the sample is a preparation of splenocytes, and the binder is a CD43 glycoform specific antibody. While Ellis et al disclose experiments that characterize the nature of a deficiency in immune cell function in transgenic mice, rather than the diagnosis of a deficiency in immune cell function, it is noted that all that is required for anticipation is that the reference show use of a binding agent to detect an altered glycosylation state in a sample that contains a plurality of glycoconjugates. All of what is recited in the preamble of claim 26 concerning “detecting a genetically transmitted deficiency in immune cell function” and in step c) concerning the “wherein” relationship do not carry patentable weight. These recitations in the preamble and step c) merely pertain to the

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recognition of a scientific principle and a mental step that relates the detected binding to a clinical condition, based upon the scientific principle. Applicant's basic discovery (e.g. pg 14, lines 24+) may be of academic interest but does not provide the basis for patentability, as long as a detection method in accord with steps a) and b) of claim 26 and in accord with the "detecting" feature of claim 58 is shown in the prior art.

Claims 26, 53-55, 58 and 68-69 are rejected under 35 U.S.C. 102(b) as being entirely anticipated by Fukuda (5,320,943) in light of The Merck Manual.

Fukuda discloses detection of the T-cell dysfunction known as Wiskott-Aldrich Syndrome (WAS). The dysfunction is genetically transmitted as an X-linked disorder and is characterized by immunodeficient features; see Merck Manual at pg 1038 for evidence. The disorder can be detected by virtue of a higher level of expression of the branched hexasaccharide NeuNAc.alpha.2.fwdarw.3Gal.beta.1.fwdarw.3(NeuNAc.alpha.2.fwdarw.3Gal.beta.1.fwdarw.4GlcNAc.beta.1.fwdarw.6)GalNAc-Ser/Thr on resting T-lymphocytes of WAS patients as compared to normal subjects. This increase is due to the activity a glycosyltransferase involved in the biosynthesis of a Core 2 type structure. See col. 2, lines 8-47; col. 5, lines 40-51; col. 6, lines 28-35 and 53-65; and col. 15, line 27-col. 19, line 22. The detected hexasaccharide is clearly one of a "plurality of glycoconjugates" as required by instant claim 26, step a); see Table III.

Fukuda teaches that one can detect the levels of the hexasaccharide with an antibody that binds to the hexasaccharide. See for example col. 8, lines 9-12. Such an antibody corresponds to what applicant recites as a "first type of diagnostic agent".

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From the above teachings, instant claims 26, 53-55 and 68-69 are anticipated. Regarding further dependent claim 58, the T-305 monoclonal antibody of Fukuda is specific for a high mw glycoform of leukosialin/CD43; see col. 16, lines 53-59. Note teachings at col. 4, lines 57-58 and 64-65 concerning the equivalence of "leukosialin" and CD43.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 5/25/06 DAS



DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182-1644